

Interpretive Guidance Document for Assessment of Polymers

Updated June 2006

This document was developed to help interpret estimation results from U.S. EPA's Sustainable Futures (SF) / P2 Framework methods and is used during SF hands-on training in the proper use of the methods.

Participants in the voluntary Sustainable Futures Initiative are asked to submit the information contained in this worksheet along with their SF PMNs in the submitter's choice of format.

NOTE: Due to the dynamic nature of the Internet, the URLs listed in this document may have changed. A search using any of the publicly available search engines should locate the new URL.

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The following document is designed to be a teaching aid in the P2 Framework assessment of polymers. The properties and hazards listed here should be used only as general guidelines for assessment of polymers of similar type. Some polymers may be outside the scope of this document. In no way should these estimates be used in lieu of measured data on the polymer under assessment. In addition, data available for structurally similar polymers may be more accurate than assessments based on this document. This document is intended for use primarily with large polymers of $MW_n > 1000$. For polymers with $MW_n < 1000$ these materials may be assessed as a discrete, representative structure using EPI Suite and/or ECOSAR. The main source of data for this document is: Boethling, Robert S. and Nabholz, J. Vincent "Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act", pp. 187-234, in Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, John D. and Sutcliffe, Roger (eds.), (1997) Van Nostrand Reinhold.

Topic	Page
Availability of Sustainable Futures / P2 Framework Models.....	2
Average Molecular Weight (MW_n) and Low Molecular Weight (LMW) Material Composition Categories ...	3
Estimating Physical/Chemical Properties	4
Important Physical-Chemical Properties.....	4
General Physical-Chemical Properties	4
Environmental Fate Assessment	5
Estimating Aquatic Toxicity	6
SAR Equations for Estimating Aquatic Toxicity of Polycationic Polymers.....	8
Estimating Human Health Hazards.....	10
References Cited	11

Availability of Sustainable Futures / P2 Framework Models

EPISuite™ - download at no cost from <http://www.epa.gov/opptintr/exposure/docs/episuite.htm>

ECOSAR - download at no cost from <http://www.epa.gov/opptintr/newchems/tools/21ecosar.htm>

PBT Profiler - use on-line at no cost at www.pbtprofiler.net

OncoLogic™ - U.S. EPA has purchased the commercial rights to OncoLogic and is updating the SF website to include the downloadable version of OncoLogic. If you are attending an SF workshop, the CD received during the training seminar contains the OncoLogic Program.

ChemSTEER - download at no cost from <http://www.epa.gov/opptintr/exposure/docs/chemsteer.htm>

E-FAST - download at no cost from <http://www.epa.gov/opptintr/exposure/docs/efast.htm>

AVERAGE MOLECULAR WEIGHT (MW_n) AND LOW MOLECULAR WEIGHT (LMW) MATERIAL COMPOSITION CATEGORIES

Polymers can be divided into three categories by the percent content of their average molecular weight (MW_n) and low molecular weight (LMW) components. These distinctions are used to determine if the polymer should be assessed only as a polymer, or if oligomers may also need to be addressed. Monomers may need to be assessed if there is high content of residual monomer and/or the monomer has known aquatic or human health hazards. The assessment of monomer or oligomer toxicity is in addition to, or in lieu of, any polymer-specific assessment.

- Category 1, those with low molecular weight ($MW_n < 1,000$). These polymers may be able to be assessed as a single, discrete structure in EPI Suite and ECOSAR, subject to the normal limitation of the software. This is possible when the composition and structure of the polymer is known. In order to complete the assessment, find a reasonable representative structure of $MW < 1,000$ and use this in the P2 modeling programs.
- Category 2, those with high molecular weight ($MW_n > 1,000$) and large low molecular weight (LMW) material composition ($\geq 25\%$ with $MW < 1,000$; $\geq 10\%$ with $MW < 500$). These polymers can be assessed for environmental fate and toxicity as the polymer; however, oligomers may need to be assessed in addition to account for any increased toxicity due to these lower molecular weight compounds.
- Category 3, those with high molecular weight ($MW_n > 1,000$) and minimal LMW material ($< 25\%$ with $MW < 1,000$; $< 10\%$ with $MW < 500$). These are generally assessed solely as the polymer. However, as stated above, if a high percentage of unreacted monomers with potential health concerns are present, additional assessment may be required to address concerns for the monomer.

ESTIMATING PHYSICAL PROPERTIES

Specific physical-chemical properties of the polymer are very important and may be required for the assessment of the polymer. These properties are those associated with structure, size, and composition of the polymer to be assessed. In addition, some properties can be estimated based simply on the large size of the material. Properties that fall into these two categories are indicated below.

Important physical-chemical properties for polymers

- Monomers from which the polymer is created, and relative mole fraction of each monomer
- Molecular weight (MW) distribution
- Number average molecular weight (MW_n) in Daltons and how it was determined
- Oligomer content of the polymer (i.e. percentages with $MW \leq 1000$ and $MW \leq 500$)
- Physical form
- Equivalent weight of any reactive functional groups (RFG) and/or cationic charge density, which can be determined from the structure.
- Particle size distribution
- Swellability
- Water solubility or dispersability – polymers that form micro emulsions or gels may be mistaken for soluble, but may not be truly soluble.

General physical and environmental fate properties for most polymers of $>1,000 MW_n$

- Vapor Pressure $<10^{-8}$ mm Hg
- Henry's Law constant $<10^{-8}$ atm-m³/mol

ENVIRONMENTAL FATE ASSESSMENT

The most important parameters to evaluate in the fate assessment of polymers are electronic charge (density being secondary), MW_n , and solubility/dispersability.

Vapor Pressure – Polymers with $MW_n > 1000$ generally have a vapor pressure of $< 10^{-8}$ mm Hg. This indicates that the chemical is likely to exist solely as particulate matter in the atmosphere. As particulate matter, atmospheric oxidation is not expected to be a significant route of environmental removal.

Henry's Law Constant – Due to the large size and low vapor pressure of most polymers, those with $MW_n > 1000$ generally have Henry's Law constant of $< 10^{-8}$ atm-m³/mol. Due to this, volatilization from water or moist soil is not expected to occur at an appreciable rate, with half-lives for volatilization of > 1 year

Bioconcentration Factor (BCF) – Due to the large size and insolubility of most polymers, they are typically of low concern for bioconcentration. Those with $MW_n > 1,000$ will typically be of low concern; for estimations that require a numeric BCF (E-FAST), 100, which is within the range of low BCF concern, can be used.

Soil Adsorption and Mobility

- Cationic, amphoteric, nonionic – These polymers will generally absorb strongly to soil and sediment.
- Anionic polymers – Anionic polymers usually have low sorption to soil. However, due to large size and weight parameters, these materials may still have low mobility in soil.

POTW removal – Removal of polymers in sewage treatment is dependent primarily on solubility, but may be influenced by binding potential for sludge.

- Cationic, Amphoteric, and Nonionic

<u>MW_n</u>	<u>Removal</u>
500 – 1,000	50 – 90% (50% typically used)
> 1000	90%
- Anionic
 - If solubility and/or dispersability are negligible, use table for cationic, amphoteric, and nonionic polymers above.
 - If soluble and/or dispersible

<u>MW_n</u>	<u>Removal</u>
$< 5,000$	0 – 50% (0% typically used)
5,000 – 20,000	50%
20,000 – 50,000	75%
$> 50,000$	90%

Biodegradation – The vast majority of polymers are essentially non-biodegradable. While some exceptions exist, these polymers are usually specifically designed to be biodegradable materials (to replace more resistant polymers as a more environmentally friendly alternative). Often, to substantiate this claim, biodegradation studies are available on these biodegradable types of polymers. In the case of highly degradable polymers, assessment of the degradation products may be warranted.

Hydrolysis – Hydrolysis of susceptible groups on polymers is solubility dependent. Polymers with poor water solubility may have reduced susceptibility to hydrolysis.

ESTIMATING AQUATIC TOXICITY

Average Molecular Weight (MW_n), Monomer, and Low Molecular Weight (LMW) Material Composition Categories – When assessing polymers that fit into category 1 above, it may be more relevant to find a discrete representative structure with MW of <1,000 and assess this structure using ECOSAR or other methods of aquatic hazards estimation. Polymers that fit into category 2 above may require assessment of the polymer itself, but further assessment of the low molecular weight components of the polymer mixture may also be needed to fully characterize the aquatic hazard. If no data on the compound are available, ECOSAR or other methods for aquatic hazard estimation can be used to assess the LMW components. Lastly, polymers that contain large amounts of residual monomers may require assessment of the monomer to fully characterize the aquatic hazards associated with the mixture.

Insoluble Polymers – Insoluble polymers are not expected to be toxic unless the material is in the form of finely divided particles. Most often, the toxicity of these polymer particles does not depend on a specific reactive structural feature, but occurs from occlusion of respiratory organs such as gills. For these polymers, toxicity typically occurs only at high concentration; acute toxicity values are generally >100 mg/L and chronic toxicity values are generally >10 mg/L (low toxicity).

Nonionic Polymers – These polymers are generally of low concern for aquatic hazard, due to negligible water solubility. Two exceptions exist. The first is for nonionic polymers that have monomers blocked in such a way as to use the polymer as a surfactant or dispersant, which may cause toxicity to aquatic organisms. The second is for nonionic polymers with significant oligomer content (ie. ≥25% with MW <1,000; ≥10% with MW <500), which may be a concern on the basis of bioavailability of the LMW material. In this case the LMW oligomers, if they are <1,000 MW, can be assessed using ECOSAR or other methods for aquatic hazard assessment.

Anionic Polymers – Polyanionic polymers with MW_n >1,000 that are soluble or dispersible in water may pose a concern for direct or indirect toxicity. These polymers are further divided into 2 subclasses: **Poly(aromatic acids)** and **Poly(aliphatic acids)**.

- **Poly(aromatic acids)** – These chemicals are usually poly(aromatic sulfate/carboxylate) structures and generally are of moderate hazard concern to aquatic organisms, with acute LC₅₀/EC₅₀ values between 1 mg/L and 100 mg/L, depending upon the exact structure of the polymer. Monomers associated with toxicity include: carboxylated/sulfonated diphenolsulfones, sulfonated phenols, sulfonated cresols, sulfonated diphenylsulfones, and sulfonated diphenylethers. Monomers usually associated with low aquatic toxicity concern include: sulfonated naphthalene and sulfonated benzene.

The toxicity of this type of polymer appears to be moderate and not affected by water hardness. Toxicity can be estimated by a nearest analog approach using test data available for polymers of known composition. A collection of data on polymers of this type is available in table 10.4 (pp. 207 – 208) in the Boethling, Nabholz reference cited above.

- **Poly(aliphatic acids)** – This type of polymer is made up of repeating carboxylic acid, sulfonic acid, and/or phosphinic acid monomers. At pH 7 this polymer type generally exhibits low toxicity toward fish and daphnid, with LC₅₀ values >100 mg/L. However, there may be toxicity hazard concerns for green algae; toxicity to algae is believed to arise from chelation of nutrients.

The toxicity of this type of polymer can be assumed to be low for fish and daphnid. Green algae toxicity can be determined using a nearest analog approach with test data collected for similar polymers of known composition. The toxicity is highly dependent on the structure of the polymer, with space between repeating acid units and addition of non-chelating groups affecting toxicity. A collection of data on polymers of this type is available in table 10.5 (pg. 209) in the Boethling, Nabholz 1997 reference on which this summary is based.

Water hardness has been shown to mitigate the toxicity of poly(aliphatic acid) polymers to green algae. As water hardness increases, toxicity tends to decrease. This is due to the abundance of chelating cations which “fill” the chelation sites of the polymer, allowing more nutrients to remain in the water. In many cases a mitigating factor can be applied to the estimated toxicity values. The appropriate mitigating factor, if any, can be discerned from table 10.6 (pg. 212) in the Boethling, Nabholz reference cited above.

Cationic Polymers – Cationic polymers that may pose a concern for aquatic hazard are those that have a net positive charge or that may become cationic in the environment.

- **Cationic Atom** - The most common atoms that may have net positive charge include, but are not limited to, nitrogen (ammonium), phosphorus (phosphonium), and sulfur (sulfonium); with nitrogen constituting the cationic atom in >99% of polymers.
- **Percent Amine Nitrogen (%A-N)** – The percent of amine nitrogen (or other cationic atom) is used in the cationic nitrogen polymer SARs for estimation of aquatic toxicity. Nitrogens directly substituted to an aromatic ring, nitrogens in an aromatic ring, amides, nitriles, nitro groups, and carbo diimides are not counted for determining %A-N.

%A-N can be determined using the following equation:

$$\%A-N = [\text{typical wt\% of amine subunit in polymer}] \times [\text{number of cationic nitrogens in subunit}] \times [\text{atomic wt of N}] \div [\text{MW of amine subunit}]$$

For smaller polymers, where the total number of nitrogens per polymer molecule is known, or non-polymers that may have toxicity similar to cationic polymers, the %A-N can be determined as:

$$\%A-N = 100 \times [\text{number of amines in compound}] \times 14.01 [\text{atomic wt of N}] \div [\text{MWn of polymer}]$$

- **Polymer Backbone** – In addition to the cation producing group, polymers of this type are assessed according to their backbone, which can be carbon-based, silicone-based (ie. Si-O), or natural (chitin, starch, tannin).
- **Cationic Polymer SARs** – The SARs for determination of aquatic hazard from cationic polymers are based on the %A-N. At high %A-N (typically 3.5% or 4.3%), it has been found that the aquatic hazard no longer correlates with increasing %A-N and is essentially constant. At this point the aquatic hazard is based on the geometric mean of similar polymers with measured data.

SAR Equations for Estimating Aquatic Toxicity of Polycationic Polymers

	Carbon-Based	Silicon-Based	Natural-Based
Fish Acute	If %A-N ≤ 3.5 ; Log [Fish 96-hr LC_{50}] = $1.209 - 0.462 \times \%A-N$ If %A-N > 3.5 ; Fish 96-hr LC_{50} = 0.28 mg/L	If %A-N ≤ 3.5 ; Log [Fish 96-hr LC_{50}] = $2.203 - 0.963 \times \%A-N$ If %A-N > 3.5 ; Fish 96-hr LC_{50} = 1.17 mg/L	Data indicate that acute toxicity toward fish will be similar or less than that for carbon-based backbone polymers. SAR analysis should employ the nearest analog method.
Daphnid Acute	If %A-N ≤ 3.5 ; Log [Daphnid 48-hr LC_{50}] = $2.839 - 1.194 \times \%A-N$ If %A-N > 3.5 ; Daphnid 48-hr LC_{50} = 0.10 mg/L	Data indicate that acute toxicity toward daphnids will be similar or less than that for carbon-based backbone polymers. SAR analysis should employ the nearest analog method.	If %A-N ≤ 4.3 ; Log [Daphnid 48-hr LC_{50}] = $2.77 - 0.412 \times \%A-N$ If %A-N > 4.3 ; Daphnid 48-hr LC_{50} = 11 mg/L
Green Algae Acute	If %A-N ≤ 3.5 ; Log [Green Algae 96-hr EC_{50}] = $1.569 - 0.97 \times \%A-N$ If %A-N > 3.5 ; Green Algae 96-hr EC_{50} = 0.040 mg/L	Data indicate that acute toxicity toward green algae will be similar or less than that for carbon-based backbone polymers. SAR analysis should employ the nearest analog method.	Data indicate that acute toxicity toward green algae will be less than that for carbon-based backbone polymers. SAR analysis should employ the nearest analog method.
Fish Chronic	Acute to Chronic Ratio (ACR) of 18	Acute to Chronic Ratio (ACR) of 18	Acute to Chronic Ratio (ACR) of 18
Daphnid Chronic	Acute to Chronic Ratio (ACR) of 14	Acute to Chronic Ratio (ACR) of 14	Acute to Chronic Ratio (ACR) of 14
Green Algae Chronic	If %A-N ≤ 3.5 ; Log [Green Algae ChV] = $1.057 - 1 \times \%A-N$ If %A-N > 3.5 ; Green Algae ChV = 0.020 mg/L	Use the SAR for methodology above for carbon-based backbone polymers	Data indicate that chronic toxicity toward green algae will be less than that for carbon-based backbone polymers. SAR analysis should employ the nearest analog method.

Amphoteric Polymers – These polymers contain both positive and negative charges in the same polymer. The toxicity of these polymers is dependent on cation to anion ratio (CAR) and the overall cationic charge density. Toxicity increases with cationic charge density and, when charge density is constant, increases with CAR. The toxicity of these polymers may be reduced by a toxicity reduction factor (TRF) calculated for each endpoint. In cases where chronic endpoints are estimated using an acute to chronic ration (ACR), apply the ACR after the TRF is applied to the acute endpoint, no further TRF is applied to the chronic endpoint.

The toxicity of these polymers is predicted in 4 steps:

- Step 1: a. Calculation of the %A-N: this is done as for cationic polymers above.
- b. Calculation of the CAR; this calculation is as follows:

$$CAR = \text{ratio of cations to anions in the chemical} = [\text{total number of cations}] \div [\text{total number of anions}]$$

Step 2: Estimate the aquatic toxicity from the %A-N as if the polymer were polycationic.

Step 3: Calculate the TRF from the CAR for each end point from the following equations:

Fish Acute TRF (96-hr LC₅₀): $\text{Log [TRF]} = 1.411 - 0.257 \times \text{CAR}$

Daphnid Acute TRF (48-hr LC₅₀): $\text{Log [TRF]} = 2.705 - 0.445 \times \text{CAR}$

Green Algae Acute (96-hr EC₅₀): $\text{Log [TRF]} = 1.544 - 0.049 \times \text{CAR}$

Green Algae Chronic (96-hr ChV): $\text{Log [TRF]} = 1.444 - 0.049 \times \text{CAR}$

Step 4: The predicted value from Step 2 is multiplied by the correct TRF to generate the final toxicity value.

Cationic and Amphoteric Polymers: Mitigation of Toxicity – Standard aquatic hazard testing media (OECD) usually has a low total organic content (TOC) which may result in artificially high toxicity of polycationic and amphoteric polymers in those media. Surface waters tend to have higher total organic content (TOC) and dissolved organic content (DOC) than what is used in standard (OECD) aquatic toxicity testing media. It has been shown that DOC, particularly humic and other acidic compounds, reduces the toxicity of cationic and amphoteric polymers to the aquatic environment. Due to this, the aquatic hazard may be over estimated in laboratory testing of this type of polymer, which, in large part is what the SAR methods are based on. In order to correct for TOC in actual surface water versus that in laboratory testing media, a mitigating factor (MF) has been calculated, based on testing done with standard media compared to testing done with media containing a standard 10 mg/L TOC as humic acid, to apply to the aquatic effect levels estimated using SAR equations. The MF is dependent on the overall charge density, calculated as %A-N, for the polymer. Several conditions and/or structural features have been shown to affect the mitigation factor, which are discussed below.

- Mitigating Factor (MF) for Polymers that are formed by the random reaction of monomers and have minimal oligomer content (ie. <25% with MW <1,000; <10% with MW <500):

For charge density where %A-N is ≥ 3.5 : $\text{MF} = 110$

For charge density where %A-N is $3.5 - 0.7$: $\text{Log [MF]} = 0.858 + 0.265 \times \%A-N$

For charge density where %A-N is < 0.7 : Do not use a MF for these cases; MFs have not been established, but are expected to be < 7 .

- Conditions effecting Mitigation Factor (MF) value:
 - It has been shown that as LMW component composition increases, the MF decreases. For compounds with high LMW component compositions, do not apply a mitigation factor.
 - The mitigating factor has been shown to be decreased by the addition of ethoxy groups, or ethoxy ether groups, substituted directly on the nitrogen i.e. $\text{N}(\text{CH}_2\text{CH}_2\text{O})_n$, with the mitigations factor being decreased for each additional group of this type bonded to the nitrogen.

If a single ethoxy group is attached, the MF is multiplied by 0.67

If two ethoxy groups are attached, the MF is multiplied by 0.33

If three ethoxy groups are attached, the MF is essentially 0

ESTIMATING HUMAN HEALTH HAZARDS

Additional guidance on the human health assessment of polymers is available from the EPA's Pollution Prevention (P2) Manual. The most recent version is available online at: <http://www.epa.gov/opptintr/newchems/sustainable/p2frame-june05a2.pdf>.

Non-Cancer Human Health Hazard – The approach for assessing potential human health concerns posed by a polymer depends on the type and availability of toxicity data. In most cases, there is a paucity of data, which precludes adequate evaluation of the polymer itself, and requires an assessment based on information available for, e.g., close analogs, chemical class, or the constituent monomer(s). The following text presents a hierarchical approach often used in evaluating the human health effects of polymers.

Assessment based on toxicity data for the polymer or analog of the polymer – For some polymers, adequate toxicity data exist in the literature or are supplied by the submitter for assessing the potential health effects of the polymer. In this case, systemic effects, as well as portal of entry effects, are thoroughly evaluated based on data for the polymer itself. In the absence of adequate data on the polymer, or to fill specific data gaps, the assessment will be based on structurally related analog(s) that have adequate toxicity information.

Assessment based on chemical class information – Often, either no toxicity data are available or the data may be inadequate for thorough evaluation of the health effects of the polymer. For these polymers, several lines of evidence are used in parallel. The assessment may be based on the toxicity information available for the chemical class. For example, if a polymer has a structure similar to that of amphoteric surfactants, the toxicity of the polymer may be assessed based on information available for such surfactants. The toxicity of a polymer may also be evaluated based on its intended use. For example, if the polymer is a chelating agent, the assessment will consider the toxicity information available for such agents based on their functional effect. The evaluation should also take into consideration the presence of reactive functional groups (RFGs) on the side chains. A key consideration is whether these side chains are likely to have biological functions in the context of their presence on a larger molecule (since they may not be available for interaction with the same cellular targets as a small molecule would be with the same structure). Additionally, if the polymer is expected to undergo hydrolysis (in the environment, under physiological conditions such as the acidic pH of the stomach, or enzymatically), the evaluation of the health effects should take into consideration the toxicity data available for the hydrolysis product(s). If hydrolysis is expected, then the toxicity assessment may also need to consider potential toxicity of the hydrolysis products. In other instances, the size or chemical properties (e.g., solubility) of the polymer will raise the question regarding its bioavailability. Typically, polymers with molecular weight <1000 are considered to be of limited bioavailability. If it is known, or if there is evidence to suggest that the polymer is not bioavailable, the evaluation will be limited to consideration of portal of entry effects.

Assessment based on residual monomers – It may also be appropriate to develop an assessment based on the toxicity information of the low molecular weight species or residual monomers if they exist in a product at significant quantities (e.g., >10%).

Lung Effects of High Molecular Weight Polymers – Polymers with MW_n of >10,000 are generally of concern only for lung effects. For concerns specific to lung toxicity, these polymers are typically divided into 3 classes; soluble, insoluble, and swellable. The associated hazard concerns are qualitative, rather than quantitative, and are used to identify inhalation concerns. Additional guidance on the human health assessment of high molecular weight polymers is available online from the EPA at: <http://www.epa.gov/opptintr/newchems/hmwtpoly.htm>.

- **Soluble** – Soluble polymers of MW_n 10,000 – 13,000 are not expected to exhibit lung toxicity because they can rapidly clear from the respiratory tract, preventing lung overload. However, soluble polymers of MW_n >13,000 may have the potential to cause lung overloading effects. Polymers that are soluble as well as swellable (tea bag test shows loss of material) are considered soluble for the determination of lung effect concerns.

- **Insoluble** – There are concerns for insoluble polymers with $MW_n > 10,000$ for the potential to cause lung overloading. Studies have shown irreversible lung damage as a result of respiration of polymer particles with $MW_n > 70,000$. Additional concerns exist for ultra-fine particles with significant amounts of < 10 micron material.
- **Swellable** – Polymers of this type that can absorb their weight or greater in water have serious health concerns for fibrosis and/or cancer.

Cancer Human Health Hazard – OncoLogic may be used to assess the potential human health cancer concerns for polymers. The assessment uses input on basic properties, structural features, and components of the polymer; not all of these properties are required, however, more data input will lead to a more accurate assessment of the potential carcinogenic effects. In addition, the software goes through several yes or no questions to help in the assessment. The data needed, as well as many of the questions that will be asked, are listed below.

- Average molecule weight (MW_n)
- Is the polymer made of covalently linked repeating units?
- Does the polymer contain $> 2\%$ residual monomer?
- Does the polymer contain $> 2\%$ material with $MW \leq 500$?
- Does the polymer contain any of the following atoms: Beryllium (Be), Cadmium (Cd), Chromium (Cr), Nickel (Ni), Arsenic (As), Antimony (Sb)?
- Is the polymer crosslinked?
- Any reactive functional groups (RFGs) on the polymer or unreacted monomers should be included.
- Water solubility of the polymer.
- Is the polymer expected to be inflammatory?
- Is the polymer expected to accumulate in soft tissues?
- What routes of exposure (ingestion, injection, or inhalation) are expected? Is the polymer going to be in a form that is easily respirable?

REFERENCE CITED

Boethling, Robert S. and Nabholz, J. Vincent "Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act", pp. 187-234, in Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, John D. and Sutcliffe, Roger (eds.), (1997) Van Nostrand Reinhold.